IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	BICKFORD SMITH, Philip et al.
Application Serial Number	:	10/532,772
Application Filing Date	:	April 21, 2005
Title	:	Medical Small-Bore Tubing System and Kit
Examiner	:	Anderson, Michael J.
Art Unit	:	3767

PRE-APPEAL BRIEF REQUEST FOR REVIEW
TRANSMITTAL LETTER

Applicant requests review of final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets (5).

I am the

☐ applicant/inventor Signature /Marc Karish/

☐ assignee of record of the entire interest Printed name Marc Karish

☒ attorney or agent of record, Reg. No. 44,816 Telephone No. 626-796-4000

☐ attorney or agent acting under 37 CFR 1.34, Date March 28, 2008

Reg. No. 44,816

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REASONS IN SUPPORT OF THE ATTACHED PRE-APPEAL BRIEF REQUEST FOR REVIEW, March 28, 2008.

The Claimed Invention

The claims of this invention are directed to connectors for medical small bore tubing for multiple different applications. The connectors have a male component and a female component, each with a key, the connectors and their respective keys being unique to each application to prevent connection of a female component of one application to a male component of another application. The male and female components can be interconnected in a fluid-tight manner with inter-engagement of the keys.

At least one of the male and female components has a grip having "application affordance" unique to the application for which the components are to be used. "Application affordance" suggests appropriate usage. Application affordance informs the user of the opportunity of making a successful or unsuccessful connection, and also reminds the user of the kind of system he is attempting to connect. Thus, it is not merely a question of, for example, trying to fit a square peg in a round hole, but perhaps more importantly trying to fit a neuraxial connector intended for spinal applications into a respiratory system. The appropriate key should prevent this from happening. However, the visual and tactile cues also serve to prevent attempts from being made to overcome the mechanical keys (such as by over wrapping with flexible tape, to act as a conduit) and to draw attention to the attempted misconnection.

As explained in paragraphs 20 to 22, the claimed application affordance is highly advantageous, because it prevents not only misconnections, but the lost time and effort associated with attempted misconnections. Moreover, the application affordance comprises tactile cues, thereby allowing for connections to be made blind, such as under the sheets of a hospital bed.

Rejection of Claims 1 to 16, 18 to 27, 29 and 31 Under 35 U.S.C. §102

Claims 1 to 16, 18 to 27, 29 and 31 are rejected under 35 U.S.C. §102(b) as being anticipated by Segal et al. (U.S. Patent No. 6,402,207). Claim 1 recites where "said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues." Segal et al. fail to teach or suggest this limitation. As explained in the specification in paragraphs 78 to 80, the application affordance can comprise, for example, a shape suggestive of a human spine and rib cage for neuraxial uses; a bellows-like shape suggestive of air flow for respiratory applications; and a bulbous shape suggestive of a human colon for enteral applications.

Segal et al. disclose a connection system having converters with standard luer connections, and different interconnections. A key is provided in the form of surface features that prevent incorrect connections. The surface features may be geometric shapes, such as triangles, squares, pentagons, hexagons, or other regular polygon or quadrilateral shape. See, col. 6, lines 43 to 47. "The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from the distinctive markings on the outer surfaces of the half connectors. These markings can include texture features, color-coding and/or text labels, such as labels 70." See, col. 5, lines 41-45.

However, there is no intuitive guidance proposed to ensure recognition. Recognition is only gained by learning the shape or color coding, or by reading the labels. In contrast, the present invention employs application affordance that guides the user subconsciously and consciously to correct recognition. Users of connectors having application affordance do not have to learn shape or color coding and do not have to read the labels, because the shape of the grip identify the proper application. Thus, Segal et al. fail to teach or suggest application affordance as claimed. Accordingly, claim 1 is patentable over Segal et al.

Claims 2 to 16, 18 to 27, 29 and 31 depend from claim 1 and are patentable over Segal et al. for the reasons given above for claim 1 as well as because of the additional limitations contained therein. For example, claim 2 further recites "wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended." The Examiner states that Segal et al. teach this limitation in col. 8, lines 33 to 49. The portion cited by the Examiner is reproduced below for convenience:

> The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in FIG. 1 into a standard medical connector or device. FIGS. 7A through 7D illustrate the incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This connector half includes a complementary shaped surface feature that ensures that only medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Applicants respectfully submit that neither the portion cited by the Examiner, nor the remainder of Segal et al. teach or suggest "a shape of the grip that is suggestive of a part of a human body for which the application is intended" as claimed. None of the shapes illustrated by Segal et al. is suggestive of a part of a human body, and nowhere does Segal et al. suggest that shapes suggestive of a part of a human body are possible or desirable.

Claim 3 further recites "wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs." One embodiment of such a grip shape is shown in Fig. 5a. The Examiner cites to the portion reproduced above, col. 8, lines 33 to 49 and to Fig. 7A for teaching this limitation. Applicants respectfully submit that neither the portion cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitation. A review of Fig. 7A reveals a cylindrical grip having an indented portion. The grip shown in Fig. 7A is not "suggestive of a human spine

and ribs" as claimed.

Claim 4 further recites, "wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows." Claim 5 further recites "wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon." In rejecting both claims 4 and 5, the Examiner cites to Figures 5 and 7, col. 6, lines 37 to 64, and column 8, lines 33 to 49. Neither the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitations of claims 4 and 5.

Claim 8 further recites, "wherein said method of interconnection comprises a twisting step; and wherein said mechanism affordance comprises a wing of said grip." Claim 9 further recites, "wherein said method of interconnection comprises a pushing step; and wherein said mechanism affordance comprises a waist of said grip." Claim 10 further recites, "wherein said method of interconnection comprises a locking step; and wherein said mechanism affordance comprises a button of said grip." "Mechanical affordance" means structure that leads a user to the appropriate action, much as a doorplate invites a user to push the door or a handle invites a user to pull without any requirement for labels saying "push" or "pull".

The Examiner cites the same elements of Segal et al., namely Figure 2, elements 29 and 35 as teaching all of the limitations of claims 8, 9, and 10. Applicants respectfully submit that elements 29 and 35 are not wings, a waist or a button, and therefore fail to teach or suggest the above limitations of claims 8 to 10. Moreover, Applicants submit that the rejection is improper as citing the same elements for teaching three different structures.

Accordingly, Applicants respectfully request that the rejection of claims 1 to 16, 18 to 27, 29 and 31 under 35 U.S.C. §102(b) be withdrawn.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 17 and 28 to 30 under 35 U.S.C. §103(a) as being unpatentable over Segal et al. (U.S. Patent No. 6,402,207 in view of Moberg et al. (U.S. Patent No. 6,659,980). Claims 17 and 28 to 30 depend from claim 1 and by definition contain all of the limitations of claim 1. As explained above with regard to claim 1, Segal et al. fail to teach or

suggest wherein "said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues." Moberg et al. fail to remedy the defects of Segal et al.

Moberg is directed to improvements in infusion pumps. The Examiner cites to Moberg et al. for teaching ultrasonic welding and adhesion. However, Applicants respectfully submit that Moberg et al. fail to teach or suggest wherein "said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues."

Accordingly, Applicants respectfully submit that claim 1 is patentable over Segal et al. and Moberg et al., both alone and in combination. Claims 17 and 28 to 30 are patentable over Segal et al. and Moberg et al. for the reasons given above for claim 1 as well as because of the additional limitations contained therein.

Accordingly, Applicants respectfully request that the rejection of claims 17 and 28 to 30 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants believe that all pending claims are in condition for allowance and Applicants respectfully request that a Notice of Allowance be issued for this application. If, however, there are any outstanding issues that could usefully be discussed by telephone, then the panel is asked to call the undersigned. Applicant reserves the right, if an Appeal is necessary, to present arguments going beyond the content of this request.

Respectfully Submitted,

SHELDON MAK ROSE & ANDERSON

Date: March 28, 2008

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